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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,273	12/12/2001	Alasdair Mark Naylor	PC22013AADO	7030

7590 07/15/2005

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EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/017,273	NAYLOR ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7,9,11,13,17-23,25,28-35 and 37-43* is/are pending in the application.

4a) Of the above claim(s) *11,17-23,25,28-32 and 39-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7,9,13,33-35,37 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments filed April 11, 2005 have been entered. The cancellation of claims 3-6, 8, 14-16, 24, 36, and 44 is acknowledged. Claims 7, 9, 11, 13, 17-23, 25, 28-35, 37-43 are pending.

Claims 11,17-23, 25, 28-32, and 39-43 pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made with traverse in Paper No. 11.

The outstanding rejections under 35 USC 103 and 12 are withdrawn in view of the amendments filed April 11, 2005.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 9, 13, 33-35, and 37-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The instant claims are drawn to the "prevention" of male erectile dysfunction (hereinafter MED). The instant specification does not provide information for one of skilled in the art to "prevent" MED in patients that are not suffered from it. The term "prevent" construed as an absolute prevention for MED. It is known in

the art that the impotence has numerous etiologies such as alcoholism, neurogenic disorders, intrappsychic factors including abnormal fear of vagina, sexual guilt, depression, and fear of intimacy (See Merck Manual, 16th ed., 1992, page 1575 – 1576). The instant specification does not provide sufficient guidance as to how to keep the etiologies from being manifested into MED.

Examiner notes that Merck Manual is reference of record.

Claims 34-35, 37-38 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the agents disclosed in the instant specification, does not reasonably provide enablement for other secondary agents recited. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In the instant case, the instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation. Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence or absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art,

7) the predictability of the art, and

8) the breadth of the claims.

The claims are very broad that they encompass various classes of compounds. Applicant fails to set forth the criteria that defines those medicaments containing a secondary active agents that are "vasodilators", "Calcium channel blocker", "potassium channel modulators", "Thrombozane A2 agonists", "CNS active agents", "compounds which modulate the action of natruretic factors", "insulin sensitizing agents", "An NEP inhibitor", "VIP memtic, VIP analogueone", "A melanocortin receptor agonist or modulator or melancortin enhancer", "a serotonin receptor", "agonist or modulator for oxytocin/vasopressin receptors", "a purinergic receptor agonist and/or modulator", "a neurokinin receptor antagonist", "Modulators of cannabinoid receptors", "A SEP inhibitor", and "agents capable of modulating the activity of an intermediate conductance calcium-activated potassium channel in the sexual genitalia of an individual" useful for practicing the invention as claimed. Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of those "potassium channel modulators", "CNS active agents", "compounds which modulate the action of natruretic factors", "insulin sensitizing agents", "An NEP inhibitor", "VIP memtic, VIP analogueone", "A melanocortin receptor agonist or modulator or melancortin enhancer", "a serotonin receptor", "agonist or modulator for oxytocin/vasopressin receptors", "a

purinergic receptor agonist and/or modulator", "a neurokinin receptor antagonist", "Modulators of cannabinoid receptors", "A SEP inhibitor", and "agents capable of modulating the activity of an intermediate conductance calcium-activated potassium channel in the sexual genitalia of an individual" useful for practicing the invention as claimed examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. Examiner notes that in some cases, the instant specification does not even disclose any compounds within the particular class of compounds (e.g., CNS agents, NEP inhibitor, purinergic receptor agonist and/or modulators, agonist or modulator for oxytocin/vasopressin receptors, modulators of cannabinoid receptors, SEP inhibitors, and agents capable of modulating the activity of an intermediate conductance calcium-activated potassium channel in the sexual genitalia of an individual). The pharmaceutical art is relatively unpredictable that without sufficient guidance disclosed in the specification, one of skilled in the art will be required each embodiment to be assessed individually for physiological and therapeutic activity. The instant claims read on all those medicaments that contains "potassium channel modulators", "CNS active agents", "compounds which modulate the action of natruretic factors", "insulin sensitizing agents", "An NEP inhibitor", "VIP memtic, VIP analogueone", "A melanocortin receptor agonist or modulator or melancortin enhancer", "a serotonin receptor", "agonist or modulator for oxytocin/vasopressin receptors", "a purinergic receptor agonist and/or modulator", "a neurokinin receptor antagonist", "Modulators of cannabinoid receptors", "A SEP inhibitor", and "agents capable of modulating the activity of an intermediate

conductance calcium-activated potassium channel in the sexual genitalia of an individual" as secondary agents useful for practicing the invention as claimed, necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. The courts have recently held that "a written description of an invention involving a chemical genus, like a description of a chemical species, requires a precise definition such as by structure, formula or chemical name", *University of California v. Eli Lilly and Company* 43 USPQ 2d 1398 at 1405; a definition by function "is only a definition of a useful result rather than a definition of what achieves that result" (ibid 1406). In the instant claims, chemical species are functionally recited (the functions being 1) angiotensin II receptor antagonization coupled with 2) the implied function of treating MED but no "precise definition" by structure, formula or chemical name is set forth, and no immediately recognizable class of compounds simultaneously having functions "1)" and "2)" appears to be recognized by the art at this time. Accordingly, any compounds known to man would be candidate compounds for practicing the instant invention and thus, undue experimentation would be required to search for any and all potentially useful compounds which might (or might not) exist, with the specification providing no guidance as to the existence (or non-existence) of such speculative compounds.

In addition, for vasodilators and calcium channel blockers, it is well-known that some vasodilators and calcium channel blocker can actually cause impotence. An example for such compound is verapamil. One of its side effects is impotence (See he monograph of verapamil in PDR 1997, page 2571-2573, especially page 2573, Adverse

Reactions Section). Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

San-ming Hui
Primary Examiner
Art Unit 1617